



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Treatment of Tinnitus

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for the treatment of tinnitus. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Treatment of tinnitus with tinnitus maskers, electrical stimulation, and transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, tinnitus coping therapy, transcranial magnetic stimulation, transcutaneous electrical stimulation, sound therapy, or botulinum toxin A injections is considered **investigational**.

NOTE: This policy does not address pharmacologic treatment of tinnitus, e.g., the use of amitriptyline or other tricyclic antidepressants.

Description of Procedure or Service

A variety of non-pharmacological treatments are being evaluated to improve the subjective symptoms of tinnitus. These approaches include use of tinnitus maskers, electrical stimulation, transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, tinnitus coping therapy, transcranial magnetic stimulation, transcutaneous electrical stimulation, sound therapy, and botulinum toxin A injections.

Background

Tinnitus describes the perception of any sound in the ear in the absence of an external stimulus and presents a malfunction in the processing of auditory signals; a hearing impairment, often noise-induced or related to aging, is commonly associated with tinnitus. Clinically, tinnitus is subdivided into subjective and objective; the latter describes the minority of cases in which an external stimulus is potentially heard by an observer, for example by placing a stethoscope over the patient's external ear. Common causes of objective tinnitus include middle ear and skull-based tumors, vascular abnormalities, and metabolic derangements. In the majority of cases, tinnitus is subjective and frequently self-limited. In a small subset of patients with subjective tinnitus, its persistence leads to disruption of daily life. While many patients habituate to tinnitus, others may seek medical care if the tinnitus becomes too disruptive.

Many treatments are supportive in nature, as currently, there is no cure. One treatment, called tinnitus masking therapy, has focused on use of devices worn in the ear that produce a broad band of continuous external noise that downs out or masks the tinnitus. Cognitive behavioral therapy may also be provided to improve coping skills, typically requiring 4 to 6 one-hour visits over an 18-month period. Tinnitus retraining therapy, also referred to as tinnitus habituation therapy, is based on the theories of a researcher named Jastreboff. Jastreboff proposes that tinnitus itself is related to the normal background electrical activity in auditory nerve cells, but the key factor is the subject's unpleasant perception of the noise, which is governed by an abnormal conditioned response in the extra-auditory limbic system. The

goal of tinnitus retraining therapy is to retrain the subcortical and cortical centers involved in processing the tinnitus signals and habituate the subcortical and cortical response to the auditory neural activity. In contrast to tinnitus masking, the auditory stimulus is not intended to drown out or mask the tinnitus, but set at a level such that the tinnitus can still be detected. This strategy is thought to enhance habituation to the tinnitus by increasing the neuronal activity within the auditory system. Treatment may also include the use of hearing aids to increase external auditory stimulation.

Sound therapy is a treatment approach that is based on evidence of auditory cortex reorganization (cortical remapping) with tinnitus, hearing loss, and sound/frequency training. One type of sound therapy uses an ear-worn device (Neuromonics Tinnitus Treatment, Neuromonics, Australia) prerecorded with selected relaxation audio and other sounds spectrally adapted to the individual patient's hearing thresholds. This is achieved by boosting the amplitude of those frequencies where an audiogram has shown the patient to have a reduced hearing threshold. Also being evaluated is auditory tone discrimination training at or around the tinnitus frequency. Another type of sound therapy that is being investigated utilizes music with the frequency of the tinnitus removed (notched music) to promote reorganization of sound processing in the auditory cortex.

Transcutaneous electrical stimulation to the external ear has also been investigated and is based on the observation that the electrical stimulation of the cochlea associated with a cochlear implant may be associated with a reduction in tinnitus. Transmeatal low-power laser irradiation, electromagnetic energy, transcranial magnetic stimulation, and botulinum toxin A injections have also been evaluated.

Regulatory Status

The Neuromonics Tinnitus Treatment has been cleared for marketing as a tinnitus masker through the Food and Drug Administration's (FDA) 510(k) process, and is "intended to provide relief from the disturbance of tinnitus, while using the system, and with regular use (over several months) may provide relief to the patient whilst not using the system."

Rationale

This policy was created in 2001 and updated periodically using the MEDLINE database. The most recent review was performed through April 3, 2014.

Because tinnitus is a subjective symptom without a known physiologic explanation, randomized placebo-controlled trials are particularly important to validate the effectiveness of any treatment compared with the expected placebo effect.

In 2013, the Agency for Healthcare Research and Quality published a comparative effectiveness review on the evaluation and treatment of tinnitus.(1) Treatments evaluated included laser, transcranial magnetic stimulation (TMS), hyperbaric oxygen therapy, sound treatments, and psychological/behavioral treatments. Studies met inclusion criteria if they had a comparator or control treatment, which could include placebo, no treatment, waiting list, treatment as usual, or other intervention. Eleven studies were included on medical interventions, 4 on sound technology interventions, and 19 on psychological and behavioral interventions. The review found insufficient evidence for medical and sound technology interventions. For psychological and behavioral interventions, there was low evidence of an effect for cognitive behavioral therapy (CBT) on tinnitus-specific quality of life, and low evidence of no effect for CBT on subjective loudness, sleep disturbance, anxiety, depression, and global quality of life. Evidence was insufficient for other psychological and behavioral interventions such as tinnitus retraining therapy and relaxation.

Tinnitus Coping Therapy (Cognitive and Behavioral)

In 2012, Cima et al reported a large randomized controlled trial (RCT) of usual care versus a combination of cognitive and behavioral approaches.(2) Of 741 untreated patients who were screened, 247 were assigned to usual care (eg, hearing aids and up to 9 sessions with a social worker), and 245 were assigned to a specialized care protocol. Specialized care included 105 minutes of audiologic

diagnostics, 30 minutes of audiologic rehabilitation (hearing aid or masking device), 120 minutes of CBT education, 60 minutes of intake psychology, 40 minutes of audiologic follow-up, and 24 hours of group behavioral and cognitive therapies. About a third of the patients in each group were lost to follow-up at 12 months. Compared with usual care, the specialized care resulted in a modest improvement in health-related quality of life (effect size, 0.24), decrease in tinnitus severity (effect size, 0.43), and decrease in tinnitus impairment (effect size, 0.45). Because the specialized care protocol was an intensive, multidisciplinary intervention, it is uncertain which components of the intervention were associated with improvements in outcomes and whether such an intensive treatment could be provided outside of the investigational setting.

CBT: A 2007 Cochrane review identified 6 randomized trials in which 285 patients with tinnitus received CBT or a control condition (another treatment or waiting list).(3) Analysis found no significant effect in the subjective loudness of tinnitus or in the associated depression. However, there was an improvement in the quality of life (global tinnitus severity), suggesting that CBT has a positive effect on the way in which people cope with tinnitus. This Cochrane review was updated in 2010 with 2 additional trials and a total of 468 participants.(4) As was previously found, there was no significant difference in subjective tinnitus loudness with CBT and either no treatment or another intervention but an improvement in quality of life. The updated analysis found evidence that depression scores improved when comparing CBT to no treatment, but there was no evidence of benefit in depression scores when compared with other treatments (yoga, education, minimal contact-education).

In 2013, Zenner et al reported a multicenter pragmatic trial of a standardized individual tinnitus-specific CBT program versus a waiting-list control in 286 patients between 14 and 78 years of age.(5) Four sites enrolled patients into the CBT program, while a fifth site enrolled patients into the waiting control group. There were differences between the groups at baseline for tinnitus compensation, tinnitus quality, and tinnitus duration. In addition, the intervention group was assessed at a median of 10 weeks while the control group was assessed at a median of 24 weeks. The primary outcome measure, tinnitus change score using an 8-point numeric verbal rating scale, showed an efficacy of treatment with an odds ratio of 3.4 (95% confidence interval [CI], 2.6 to 4.5) in intention-to-treat analysis. Improvement in the tinnitus change score with a score of 2 or better was reported in 85% of CBT-treated patients compared with 22% of controls. Another primary outcome, the multivariate rank of the Tinnitus Questionnaire, tinnitus change, loudness, and annoyance scores, improved significantly in the treatment group but not in the control group. These scales appear to have been developed and tested for validity in a prior study by the authors of this report. Interpretation of this study is limited by the potential for bias in these subjective measures.

Acceptance and Commitment Therapy: In 2011, Westin et al reported an RCT of acceptance and commitment therapy (ACT) versus tinnitus retraining therapy or waiting-list control in 64 normal hearing patients.(6) The ACT treatment consisted of 10 weekly 60-minute sessions, and the tinnitus retraining therapy consisted of one 150-minute session, one 30-minute follow-up, and continued use of sound generators during waking hours for 18 months. The Tinnitus Handicap Inventory (THI) was the primary outcome measure, with assessments at baseline, 10 weeks, 6 months, and 18 months. There was a significant advantage of ACT over tinnitus retraining over time. In the ACT group, THI improved from 45.27 to 28.19 at 18 months. In the tinnitus retraining group, THI improved from 47.00 at baseline to 41.86 at 18 months, while the waiting-list control was unchanged at 48.29. Improvement on the THI was found for 54.5% in the ACT group and 20% in the tinnitus retraining group ($p < 0.04$).

Self-Help and Internet-Based Coping Therapies: A 2007 study by Kaldo et al, found that a CBT self-help book for tinnitus combined with 7 weekly phone calls from a therapist reduced distress (>50% on the Tinnitus Reaction Questionnaire[TRQ]) in 32% of subjects compared with 5% of the waiting-list control group.(7) Analysis of follow-up data suggested that a self-help book alone (provided to the control group after the study period) without therapist support might result in equivalent improvement in distress, because 26% to 28% of patients from both groups showed distress reduction at 1 year. A subsequent randomized study by Kaldo et al found that an Internet-based self-help program was as effective as standardized group-based CBT for reducing tinnitus distress.(8)

These studies were followed by a 2012 RCT of internet-delivered CBT or ACT.(9) Ninety-nine participants with moderate to severe tinnitus distress were recruited from the community and randomized to guided, self-help CBT (n=32) or ACT (n=35) format or to a control condition of a monitored internet discussion forum on tinnitus (n=32). Assessment at 8 weeks showed improvement for both of the psychological therapies compared with controls, with no significant difference between CBT and ACT. Follow-up at 1 year was conducted for the 2 psychological therapies, which remained improved over baseline. There was no follow-up at 1 year for controls.

Tinnitus Masking

A 2010 Cochrane review, with an update in 2012, evaluated evidence for masking in the management of tinnitus in adults.(10,11) Included in the review were 6 RCTs (553 participants) that used noise-generating devices or hearing aids as the sole management tool or in combination with other strategies, including counseling. Heterogeneity in outcome measures precluded meta-analysis of the data. The risk of bias was medium in 3 studies and high in 3 studies. The authors concluded that due to the lack of quality research and the common use of combined approaches (hearing therapy plus counseling), the limited data failed to show evidence of the efficacy of masking therapy in tinnitus management.

For example, Stephens and Corcoran reported on a controlled study that assigned non-hearing-impaired subjects to either a control group (n=24) with limited counseling or a treatment group consisting of counseling in addition to the use of 1 of 2 different tinnitus maskers (n=51).(12) Outcomes were assessed with a questionnaire. There were no significant differences among the control and treatment groups, leading the authors to conclude that treatment with maskers has not been found to show a significant advantage compared with counseling alone. No studies were identified that compared tinnitus masking using specialized ear-worn devices with other more widely available auditory stimuli (eg, radios or music players). Erlandsson et al performed a clinical trial in which patients were randomized to receive either a masker or sham device; those receiving the sham device were falsely told that it delivered a beneficial electrical current.(13) Treatment response was based on responses to a questionnaire focusing on both changes in tinnitus level and nonspecific effects on mood, stress, and symptoms other than tinnitus. Neither the treatment nor the placebo group reported a significant change in tinnitus intensity.

Tinnitus Retraining Therapy

While Jastreboff and Hazell had published the theoretical rationale behind tinnitus retraining therapy, no controlled trials were identified at the time this policy was created. Other articles were identified,(14-16) but these studies were either focused on tools to evaluate the results of tinnitus retraining or consisted of uncontrolled trials. A 2011 systematic review identified 3 RCTs using tinnitus retraining therapy.(17) One study did not find an improvement over an education-only intervention, and 2 provided low-quality evidence for the efficacy of an individualized multicomponent intervention that included tinnitus retraining. Additional controlled studies are described next.

The RCT by Westin et al (previously described) reported results of tinnitus retraining compared with ACT or waiting-list control in 64 normal hearing patients.(6) In this trial, tinnitus retraining was significantly less effective than ACT. The percent of patients with reliable improvement was 54.5% in the ACT group and 20% in the tinnitus retraining group ($p<0.04$), with 10% of patients in the tinnitus retraining group showing deterioration over the course of the trial. The THI improved from 45.27 to 28.19 at 18 months in the ACT group. In the tinnitus retraining group, the THI improved from 47.00 at baseline to 41.86 at 18 months, while the waiting-list control was unchanged at 48.29. These findings are limited by the lack of a placebo-control group

In 2011, Bauer and Bozoski reported a quasirandomized study of tinnitus retraining therapy in 32 patients with normal to near normal hearing (75% follow-up).(18) Group assignment was balanced by tinnitus severity on the THI, Beck Depression Inventory scores, and gender. Participants were assigned to 8 hours daily tinnitus retraining with three 1-hour sessions of individual counseling on tinnitus

retraining over 18 months, or a control arm of 3 counseling sessions that included coping techniques and sham sound therapy. Participants in the control arm were provided with a sound device and told to increase use to 8 hours per day, although the device ramped to off in 30 minutes. Participants were evaluated at 6, 12, and 18 months with a computerized test battery of questionnaires and psychophysical procedures. The primary outcome measure was the THI. Secondary outcome measures were change in global tinnitus impact, subjective tinnitus loudness rating, and objective tinnitus loudness measured by a psychophysical matching procedure. THI improved over the 18 months of the study to a similar extent for both the active and sham tinnitus retraining therapy. Subjective loudness was reduced in the tinnitus retraining group compared with controls at 12 to 18 months, but there was no between-group difference in the rating of annoyance and distress.

Another quasirandomized trial from a Veterans Administration (VA) medical center, published in 2006, compared tinnitus masking and tinnitus-retraining therapy. (19) Following initial screening for tinnitus severity and motivation to comply with the 18-month study, 59 subjects were enrolled in the tinnitus-masking condition (mean age, 61 years), and 64 were enrolled in tinnitus retraining (mean age, 59 years). Treatment included appointments with tinnitus specialists at 3, 6, 12, and 18 months to check the ear-level devices and to receive the group-specific counseling (about 4-5 hours total). At each visit, the subjects completed the THI, Tinnitus Handicap Questionnaire, Tinnitus Severity Index, and underwent tinnitus and audiologic tests. Questionnaire results showed minor to modest improvement at the 3- and 6-month follow-up for both treatment groups, slightly favoring the masking condition. After 12 months of treatment, medium effect sizes (0.57 to 0.66) were reached for the tinnitus-retraining therapy and, after 18 months of treatment, major effect sizes (0.77 to 1.26) were obtained. Post hoc analysis suggested that improvements were greatest in subjects who initially rated tinnitus as a “very big problem” with effect sizes of 2.01 for tinnitus severity and 2.05 for tinnitus handicap index. In comparison, tinnitus-masking therapy resulted in medium effect sizes (0.5 and 0.62) in this subgroup analysis. The authors noted that several confounding variables were present in this study, including differences in counseling between the 2 groups, and that a multicenter continuation study in the VA setting is being conducted. This is the only trial that met selection criteria for a 2010 Cochrane review; the summary stated that results of this single, low-quality trial suggest that tinnitus-retraining therapy is more effective than tinnitus masking, but because only a single trial was identified, and that trial had methodologic flaws particularly with respect to allocation bias, it is not possible to reach a firm conclusion regarding this treatment.(20)

In summary, the literature on tinnitus retraining therapy consists of a number of small randomized or quasirandomized controlled trials. Together, the literature does not show a consistent improvement in the primary outcome measure (THI) when tinnitus retraining therapy is compared with active or sham controls.

Customized Sound Therapy

Three randomized or pseudorandomized controlled trials have been identified on customized sound therapy.

An industry-sponsored randomized study compared treatment with a proprietary customized acoustic stimulus for tinnitus retraining or counseling alone.(21) Fifty (of 88 subjects recruited) were found to meet the inclusion/exclusion criteria. The mean length of time that their tinnitus had been disturbing was 3.6 years (range, 0.2 to 23). Patients were allocated into 1 of 4 groups, (1) customized acoustic stimulus at high intensity for 2 hours per day, (2) customized acoustic stimulus at a lower intensity, (3) tinnitus-retraining therapy with a broadband stimulator and counseling, or (4) counseling alone. Subjects were instructed to listen to the devices for 2 hours per day at the time of day when symptoms were most severe and at a level that completely (group 1) or partially (group 2) masked the tinnitus; use of the devices averaged 1.8 hours per day (range, 0.4 to 6.8). The 2 customized acoustic stimuli groups were combined in the analysis due to overlap in the self-administered stimulus intensity (absence of statistical difference between the groups). All patients lost to follow-up were included in the dataset for analysis with a “last value carried forward.” Mean scores on the TRQ improved over the 12 months of

the study for the customized acoustic stimuli. TRQ scores were not significantly improved in the control groups. At the 6-month follow-up, 86% of patients in the customized acoustic stimuli groups had met the definition of success based on 40% improvement in TRQ scores. Normalized visual analog scale (VAS) scores for tinnitus severity, general relaxation, and loudness tolerance were improved relative to both baseline and the control group's scores at 12 months. Perceived benefits were also greater with the customized acoustic stimulus.

Another publication from the developers of the device described results for the first 552 patients who had treatment at specialized clinics in Australia.(22) Patients were divided into 3 levels, based on complicating factors and proposed suitability for the treatment. Tier 1 (237 patients) did not display any nonstandard or complicating factors. Tier 2 (223 patients) exhibited 1 or more of the following: psychological disturbance, a low level of tinnitus-related disturbance (TRQ score <17) and/or moderately severe or severe hearing loss in 1 ear (>50 dB). Tier 3 (92 patients) exhibited 1 or more of the following: "reactive" tinnitus, continued exposure to high levels of noise during treatment, active pursuit of compensation, multitone tinnitus, pulsatile tinnitus, Meniere disease, and/or hearing loss of greater than 50 dB in both ears. Of the 552 patients who began therapy, 62 (11%) chose to discontinue treatment for refund, and 20 (4%) were lost to follow-up. After an average treatment duration of 37 weeks, the TRQ was reported to be improved (>40%) in 92% of tier 1 patients, 60% of tier 2 patients, and 39% of tier 3 patients. It was not reported if the reduction in symptoms persisted when treatment stopped. Controlled studies with long-term follow-up are needed to evaluate the durability of treatment and the relative contribution of generalized masking versus desensitization to these results.

Herraiz et al randomized 45 patients scoring mild or moderate on the THI (<56) to auditory discrimination training with the same frequency as the tinnitus pitch (SAME) or training on a frequency near to but not the same as the tinnitus pitch (NONSAME).(23) An additional 26 patients were included in a waiting-list control group. The auditory discrimination consisted of 20 minutes of training every day for 30 days, during which the patient had to record whether each stimulus pair was the same or different. A total of 41 patients (91%) completed training and follow-up questionnaires. Four percent of patients in the waiting-list control group reported their tinnitus to be better compared with 42% of patients reporting improvement following auditory discrimination training. The self-reported improvement in tinnitus tended to be higher in the NONSAME group (54%) in comparison with the SAME group (26%), although subjective improvement was variable, and the difference was not statistically different. The subjective improvement in VAS tinnitus intensity was modest and similar in the 2 groups (0.65 vs 0.32, respectively). The decrease in THI scores was significantly greater in the patients with NONSAME frequencies (11.31) than patients trained on SAME frequency (2.11).

In another publication from 2010, Okamoto et al reported a small (n=24) double-blinded pseudo-randomized trial that compared 12 months of listening to notched music (the tinnitus frequency was removed) or placebo music.(24) An additional group of patients who were not able to participate in the music training due to time constraints served as a monitoring control. Thirty-nine patients who met the strict study inclusion criteria were recruited; the final group sizes after dropouts and exclusions was 8 in the target-notched music group, 8 in the placebo group, and 7 in the monitoring group. After 12 months of music (approximately 12 hours per week), there was a significant decrease in tinnitus loudness (about 30%) in the target group but not in the placebo or monitoring groups. Evoked activity to the tinnitus frequency, measured by magnetoencephalography, was also reduced in the primary auditory cortex of the target group but not the placebo or monitoring groups. The change in subjective tinnitus loudness and auditory-evoked response ratio were correlated ($r=0.69$), suggesting an association between tinnitus loudness and reorganization of neural activity in the primary auditory cortex. Additional studies with a larger number of subjects are needed to evaluate this novel and practical treatment approach.

In summary, sound therapy has a solid neurophysiologic basis and the potential to substantially improve tinnitus symptoms; however, research in this area appears to be at an early stage. For example, the studies previously described use very different approaches for sound therapy, and it is not yet clear whether therapy is more effective when the training frequency is the same or adjacent to the

tinnitus pitch. In addition, patients in these studies were highly selected to maximize treatment effects. No studies from the U.S. were identified.

Transcranial Magnetic Stimulation

A 2011 Cochrane review included 5 sham-controlled trials (233 patients) with parallel groups that examined repetitive TMS (rTMS) for the treatment of tinnitus.(25) Each study described the use of a different rTMS device that delivered different frequencies ranging from 1 to 25 Hz. All of the studies were relatively small but were considered to have a low risk of bias. Four trials reported tinnitus severity and disability using the THI; only 1 study demonstrated a statistically significant improvement in THI scores. Pooled results of 2 studies that used a self-rating scale showed a statistically significant reduction in tinnitus loudness (risk ratio, 4.17; 95% CI, 1.30 to 13.40). However, the validity of these pooled results were limited, because 1 trial had a risk of selection bias and the CI of these 2 small trials (n=37 and 54) was wide. This analysis indicates that there is very limited support for the use of low-frequency rTMS for tinnitus and that larger placebo-controlled double-blind studies are needed to confirm the effectiveness of rTMS for tinnitus. Further study is also needed regarding the durability of the effect.(26)

One of the studies included in the systematic reviews was by Anders et al, who published results of a double-blinded randomized sham-controlled trial with 42 patients who had chronic, treatment-resistant tinnitus and completed 2 weeks of rTMS treatment over the left primary auditory cortex in 2010.(27) An additional 10 patients withdrew from the study before the end of treatment because of adverse effects such as headache, worsening of tinnitus, or perceived lack of efficacy. Tinnitus severity was measured at baseline, end of treatment (week 2), and during follow-up at 6, 14, and 26 weeks. The baseline THI was 37.1 for the active treatment and 26.5 for the sham treatment. At the end of the stimulation phase, both active and sham groups showed a significant reduction in the symptoms of tinnitus, as measured by the THI and Tinnitus Questionnaire. In the active rTMS group, tinnitus severity with the THI was rated as 31.8 at 2 weeks, increasing to around 33 through the 26 weeks of follow-up. In the sham group, THI was 23.1 at week 2, rising to 27.7 by 26 weeks. A similar pattern was observed with the Tinnitus Questionnaire. Interpretation of this study is limited due to the differences in baseline scores and improvement in the sham group immediately following treatment. In addition, the clinical significance of a 4-point change in the THI and 3-point change in the Tinnitus Questionnaire is unclear.

In 2013, Hoekstra et al reported results from a double-blind RCT with 50 patients treated with low-frequency rTMS or sham over the auditory cortex.(28) Follow-up at 1 week and 1, 3, and 6 months showed no benefit of rTMS over placebo on the Tinnitus Questionnaire or THI, although there was a significant interaction between treatment group and time (p=0.04 and 0.05, respectively). The interaction was due primarily to an increase in scores in the sham-control group at the 6-month follow-up, rather than improvement in the group receiving rTMS. Another small (n=19) randomized double-blinded sham-controlled parallel trial by Marcondes et al evaluated 6-month follow-up after rTMS.(29) As earlier studies showed improved outcomes in the absence of hearing impairment, only subjects with normal pure tone audiometry were included in this trial. Five sessions of rTMS (17 minutes per session) were performed on 5 consecutive business days. Placebo stimulation was performed with a sham coil system, which mimics the sound of active stimulation, without producing a magnetic field. Tinnitus severity on the THI showed a decrease from baseline (29.8) to 1-month (19.4) and 6-month (22.8) follow-up. There was no change in THI following sham stimulation (28.9 at baseline, 28.9 at 1 month, 29.6 at 6 months). At 6-month follow-up, 40% of patients receiving rTMS had a reduction greater than 10 points in the THI, compared with 22% after sham rTMS. There was a modest decrease in the mean VAS for tinnitus loudness for active rTMS, and some differences between groups in objectively measured changes in blood flow in the temporal and limbic lobes with single photon emission computed tomography imaging. Although these longer-term results are intriguing, additional studies with a larger number of subjects are needed to adequately evaluate the efficacy of this treatment.

Several sham-controlled crossover trials have also been reported (not included in the Cochrane review). One randomized, double-blind, sham-controlled crossover trial (16 patients) used low-

frequency (1 Hz) rTMS over the auditory association cortex (left temporoparietal region) for 5 days, with 2 weeks of follow-up after (and between) each condition.(30) Two patients dropped out due to worsening of tinnitus (1 from each condition); sham treatment resulted in a less than 10% improvement in VAS over the 3-week assessment. The average improvement in VAS for active rTMS (about 35%) was maintained for 1 week following treatment. Of the 14 patients who completed the study, 8 (57%) were classified as responders ($\geq 25\%$ improvement in VAS); no baseline factors were found to be associated with a positive response. Kleinjung et al reported on a placebo-controlled crossover study of low-frequency rTMS in 14 patients with chronic tinnitus.(31) Using a Magstim system, the authors applied rTMS to the area of increased metabolic activity in the auditory cortex, as identified by fused positron emission tomography and magnetic resonance imaging data. After 1 week of rTMS, 11 of 14 patients experienced a significant reduction in tinnitus ($p < 0.005$), whereas the sham treatment did not result in a significant change. Eight patients also reported reduced tinnitus 6 months after treatment.

Section Summary

The literature on rTMS for tinnitus consists of a number of small randomized sham-controlled trials with either parallel or crossover designs. Results from these trials are mixed, with some trials not finding a statistically significant effect of rTMS on tinnitus severity. Overall, the literature provides limited support for the use of rTMS. Larger controlled trials are needed to permit conclusions regarding the effect of this technology on health outcomes.

Transcranial Direct Current Stimulation

In 2012, Song et al published a systematic review of transcranial direct current stimulation (tDCS) for the treatment of tinnitus.(32) Six studies (3 open-label, 3 RCTs) were included in the review. Stimulation areas included the left temporal area and bifrontal tDCS. Overall, there was a 39.5% response rate (criteria for responder was not defined), with a mean reduction of tinnitus intensity of 13.5%. Effects were similar for stimulation over the left temporal area compared with bifrontal tDCS. Meta-analysis of 2 of the RCTs showed a medium to large effect size of 0.77.

Transcutaneous Electrical Stimulation of the Ear

Two randomized trials of electrical stimulation were reported in the 1980s with negative results. Dobie et al reported on a randomized, double-blind crossover trial in which 40 patients received an active or disconnected placebo device. Reduction in severity of tinnitus was reported in 2 of 20 patients with the active device and 4 of 20 patients with the placebo device. Fifteen of the 20 patients reported no effect with either device.(33) Thedinger et al reported on a single-blind crossover trial of 30 patients who received active or placebo stimulation over 2 weeks. Only 2 of the 30 subjects obtained a true positive result.(34) Steenerson and Cronin reported on a large case series of 500 patients with tinnitus who were treated with electrical stimulation twice weekly for a total of 6 to 10 visits.(35) Fifty-three percent of patients reported a significant benefit, defined as an improvement of at least 2 points on a 10-point scale of tinnitus intensity. Despite the favorable results, case series cannot be used as evidence of treatment efficacy, particularly when a placebo effect is anticipated. Literature review updates failed to identify any additional randomized studies that would alter the conclusions reached here. Thus, the policy statement regarding transcutaneous electrical stimulation of the ear is unchanged.

Transmeatal Laser Irradiation

A randomized study from 2002 reported that there was no significant difference in tinnitus between the active or placebo group.(36) In a 2005 update, Tauber et al reported on the use of transmeatal low-level laser therapy for the treatment of chronic tinnitus in 35 patients randomized to receive 5 single-diode laser treatments at either 635 or 830 nm.(37) The authors reported 13 of 35 patients had reduced tinnitus loudness, while 2 patients reported absence of tinnitus. However, this was not a placebo-controlled trial, and the authors noted that further study was needed. A 2008 publication of a

randomized placebo-controlled double-blind study with 60 patients reported no efficacy of laser therapy for tinnitus.(38)

Electromagnetic Energy

Ghossaini et al reported on a randomized, double-blind placebo-controlled study of 37 patients who received either placebo treatment or electromagnetic energy treatment with a Diapulse device for 30 minutes, 3 times a week for 1 month.(39) The authors found no significant changes in either group in pretreatment and post-treatment audiometric thresholds, Tinnitus Handicap Inventory scores or tinnitus rating scores, and concluded pulsed electromagnetic energy (at 27.12 MHz at 600 pulses/s) offered no benefit in the treatment of tinnitus.

Botulinum Toxin A

Stidham et al explored the use of botulinum toxin A injections for tinnitus treatment under the theory that blocking the autonomic pathways could reduce the perception of tinnitus.(40) In their study, 30 patients were randomized in a double-blind study to receive either 3 subcutaneous injections of botulinum toxin A around the ear followed by placebo injections 4 months later or placebo injections first followed by botulinum toxin A. The authors reported 7 patients had reduced tinnitus after the botulinum toxin A injections, which was statistically significant when compared with the placebo groups in which only 2 patients reported reduced tinnitus ($p < 0.005$). The tinnitus handicap inventory scores were also significantly decreased between pretreatment and 4 months postbotulinum toxin A injections. However, no other significant differences were noted when comparing the treatments at 1 and 4 months after injections. The authors noted that larger studies are needed. Also, study limitations including size and lack of intention-to-treat analysis limited interpretation of the results.

Summary

A variety of treatments have been evaluated for the treatment of tinnitus. Cognitive and behavioral coping therapies have been reported to reduce tinnitus impairment and improve health-related quality of life. One large, well-conducted randomized controlled trial (RCT) using an intensive, multidisciplinary intervention showed improvement in outcomes, but it is uncertain if the intensive treatment approach used could be replicated outside of the investigational setting. Other RCT results suggest that a self-help/internet-based approach to cognitive and behavioral therapy or acceptance and commitment therapy (ACT) may also improve coping skills. Additional studies are needed to determine the most effective method of delivering psychological coping therapy outside of the investigational setting. As a result, tinnitus coping therapy, such as cognitive behavioral interventions and ACT, are considered investigational.

Current evidence is insufficient to show improved health outcomes in patients treated with tinnitus maskers, electrical stimulation, transmeatal laser irradiation, electromagnetic energy, tinnitus-retraining therapy, sound therapy, transcranial magnetic stimulation, transcutaneous electrical stimulation, or botulinum toxin A injections. Therefore, these treatments are considered investigational.

Medicare National Coverage

The Centers for Medicare and Medicaid has a longstanding national coverage determination for tinnitus masking. This is considered an experimental therapy because of the lack of controlled clinical trials demonstrating effectiveness and the unstudied possibility of serious toxicity in the form of noise-induced hearing loss. Therefore, it is not covered.

References

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Billing Coding/Physician Documentation Information

There are no specific CPT codes for electrical stimulation or tinnitus-retraining therapy. The CPT codes used may include evaluation and management CPT codes or possibly the physical medicine and rehabilitation code 97014 (application of a modality to one or more areas; electrical stimulation) or speech therapy (92507). As tinnitus-retraining therapy in part involves counseling, an individual psychotherapy CPT code may be used (code range 90804-90809). Tinnitus-retraining therapy may also be billed as physical or speech therapy.

As described in the literature, electrical stimulation is an office-based procedure, but if self-administered by the patient, the device could possibly be described by HCPCS code E0720 (transcutaneous electrical nerve stimulation, two-lead, localized stimulation).

Tinnitus-masking devices represent a piece of durable medical equipment. There is currently no specific HCPCS code describing these devices.

There is a specific CPT code for tinnitus assessment – 92625 Assessment of tinnitus (includes pitch, loudness matching, and masking)

Policy Implementation/Update Information

9/1/08	New policy; considered investigational.
9/1/09	No policy statement changes.
9/1/10	Policy statement revised to list tinnitus coping therapy, transcutaneous electrical stimulation, and sound therapy as investigational.
9/1/11	No policy statement changes.
9/1/12	No policy statement changes.
9/1/13	No policy statement changes.
9/1/14	No policy statement changes.

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